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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,922	04/30/2001	Masayuki Fukumura	4001-0003CIP	2336

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EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/843,922	FUKUMURA ET AL.	
	Examiner	Art Unit	
	Robert M. Kelly	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-18 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-18 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/20/05; 10/28/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and argument of 1/5/06 is entered.

It is noted that the co-filed terminal disclaimer of 1/5/06 has been accepted.

Claim 16 has been amended.

Claim 22 is newly presented.

Claims 16-18 and 22 are presently pending and considered.

Double Patenting, NonStatutory – old rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

In light of Applicant's terminal disclaimer, approved 6/22/05, the provisional rejection of Claim 16 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 09/728,207, is withdrawn.

Double Patenting, NonStatutory – old rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

In light of Applicant's terminal disclaimer, approved 6/22/05, the rejection of Claim 16 under the judicially created doctrine of double patenting over claim 1 of copending Application No. 10/444,661, is withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-18 and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 9-11 of U.S. Patent No. 6,723,532 in view of any one of (i) Kobayashi, et al. (1997) Exp. Brain Res., 116 : 315-325; (ii) Hudgins, et al. (1998) Exp. Neurol., 150: 171-82; (iii) Duckett, et al. (1996) EMBO. J., 15(11): 2685-94; (iv) Datta, et al. (1997) J. Biol. Chem., 272(3) : 1965-69; (v) Srinivasula, et al. (1996) Proc. Natl. Acad. Sci., USA., 93: 14486-91; (vi) Schendel, et al. (1997) Proc. Natl. Acad. Sci., USA, 94: 5113-18; or (vii) Winkler, et al. (1998) Brain Res., 788: 1-2; (viii) Clements, et al. (1999) Oncogene, 8(5): 1311-16; or (ix) Hearn, et al. (1998) Dev. Biol., 197: 93-105; or (x) Teng, et al. (1998) Eur. J. Neurosci., 10: 798-802.

Applicant's claims 16-18 and 22 are drawn to sendai virus vectors comprising a transgene between the R1 and R2 loci, which transgene may be one of several genera or specific members of the genera. Moreover, the specification teaches the various modifications claimed in the Patent (e.g., p. 6, paragraph 2)

Claims 1-3 of the Patent claim specific sendai viral vectors comprising a transgene, which vectors are modified to contain specific deletions/inactivations of genes to provide for replication incompetence. Claim 8 teaches a method of preparing a foreign protein using the vectors in a cell, thereby making a recombinant protein. Moreover, the specification teaches that such vectors are highly useful for practical applications (ABSTRACT), which indicates that such methods of making recombinant proteins is highly useful. However, the patent does not teach the specific genera or specific genes which are presently claimed.

However, each of the references teaches the use of recombinant proteins encompassing at least one of the specific proteins claimed, and therefore falling into the various genera claimed in the claimed (*See* ABSTRACTS).

Hence, at the time of invention it would have been obvious to make the claimed invention in light of the patent and any one of the other references. The Artisan would have been motivated to do so as production of proteins are taught by the Patent to be highly useful using the vectors. Moreover, the Artisan would have had a reasonable expectation of success, as each protein had been made recombinantly, and the sendai vectors are highly useful for making such proteins.

Claim Rejections - 35 USC § 112 – enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In light of Applicant's amendments, the rejections of Claims 16-18 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a sendai viral vector comprising a heterologous encoding sequence inserted between the R1 and R2 loci, which encodes a protein capable of protecting rodent pyramidal cells of the hippocampus, by direct administration to such cells, from delayed cell death due to short-term ischemic insult, which heterologous encoding sequence encodes FGF-1 or GDNF, does not reasonably provide enablement for any cell type, or any sequence encoding any protein capable of protecting the brain from ischemia, are withdrawn.

Specifically, Applicant has removed the limitation "a protein capable to protect the brain from ischemia", and as such, the *in vivo* use is no longer required to be enabled. Applicant has clearly shown that these proteins can be expressed in brain cells *in vitro*, and as such, the claims are enabled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-18 and 22 are rejected under 35 U.S.C. 103(a) as being obvious over either of (i) Hearn, et al. (1998) Dev. Biol., 197: 93-105; (ii) Teng, et al. (1998) Eur. J. Neurosci., 10: 798-802, and U.S. Patent No. 6,723,532 to Nagai, et al.

The applied reference (US Pat No 6,723,532) has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same

party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Hearn and Teng teach the use of recombinant FGF-1 (Teng), FGF-2 (Teng) or GDNF (Hearn) in experiments (ABSTRACTS). However, neither reference teaches making these proteins recombinantly using a sendai viral vector wherein the transgene is placed between the R1 and R2 loci.

On the other hand, Nagai teaches Sendai viral vectors which are highly useful for practical applications (ABSTRACT), including the production of proteins recombinantly (col. 9, paragraphs 3-4). Such transgenes are taught to be placed between the R1 and R2 loci (col. 10, paragraph 4).

Hence, at the time of invention by Applicant, it would have been obvious to modify the methods of either Hearn or Teng, by making the recombinant proteins via the sendai viral vectors as taught by Nagai. The Artisan would have been motivated to do so because Hearn had taught such vectors and methods highly useful. Moreover, the Artisan would have had a reasonable expectation of success, as Hearn/Teng had demonstrated that the proteins could be produced recombinantly for the uses, and Nagai had taught that the method was highly useful for creating recombinant proteins.

Claim Rejections - 35 USC § 103

Claims 16-18 rejected under 35 U.S.C. 103(a) as being obvious over Clements, et al. (1999) Oncogene, 8(5): 1311-16 and U.S. Patent No. 6,723,532 to Nagai.

The applied reference has a common assignee and inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Clements teaches making FGF-5 recombinantly for binding studies. However, Clements does not teach using Sendai viral vectors comprising the transgene between the R1 and R2 loci to do so.

On the other hand, Nagai teaches Sendai viral vectors which are highly useful for practical applications (ABSTRACT), including the production of proteins recombinantly (col. 9,

paragraphs 3-4). Such transgenes are taught to be placed between the R1 and R2 loci (col. 10, paragraph 4).

Hence, at the time of invention by Applicant, it would have been obvious to modify the methods of Clements, by making the recombinant proteins via the sendai viral vectors as taught by Nagai. The Artisan would have been motivated to do so because Nagai had taught such vectors and methods highly useful. Moreover, the Artisan would have had a reasonable expectation of success, as Clements had demonstrated that the proteins could be produced recombinantly for the uses, and Nagai had taught that the method was highly useful for creating recombinant proteins.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being obvious over any one of (i) Kobayashi, et al. (1997) Exp. Brain Res., 116 : 315-325; (ii) Hudgins, et al. (1998) Exp. Neurol., 150: 171-82; (iii) Duckett, et al. (1996) EMBO. J., 15(11): 2685-94; (iv) Datta, et al. (1997) J. Biol. Chem., 272(3) : 1965-69; (v) Srinivasula, et al. (1996) Proc. Natl. Acad. Sci., USA., 93: 14486-91; or (vi) Schendel, et al. (1997) Proc. Natl. Acad. Sci., USA, 94: 5113-18; or (vii) Winkler, et al. (1998) Brain Res., 788: 1-2, and U.S. Patent No. 6,723,532 to Nagai, et al.

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Each of references (i)-(vi) teach the use of recombinantly produced proteins, including, respectively, BDNF, CNTF, IAP, p35, CrmA, and Bcl-2. However, none of these proteins teach the use of sendai viral vectors to produce such proteins where the transgene is between loci R1 and R2.

On the other hand, Nagai teaches Sendai viral vectors which are highly useful for practical applications (ABSTRACT), including the production of proteins recombinantly (col. 9, paragraphs 3-4). Such transgenes are taught to be placed between the R1 and R2 loci (col. 10, paragraph 4).

Hence, at the time of invention by Applicant, it would have been obvious to modify the methods of any of references (i)-(vi), by making the recombinant proteins via the sendai viral vectors as taught by Nagai. The Artisan would have been motivated to do so because Nagai had taught such vectors and methods highly useful. Moreover, the Artisan would have had a reasonable expectation of success, as references (i)-(vi) had demonstrated that the proteins could be produced recombinantly for the uses, and Nagai had taught that the method was highly useful for creating recombinant proteins.

For the following rejections, it is noted that Applicant has supplied a copy of the Japanese Document No. 10204333, however such document is not also provided with an English translation, and therefore, the priority is not perfected. Applicant may overcome this rejection by perfecting the priority, demonstrating the claimed invention was possessed and fulfills the requirements of 112/1st paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,514,728 to Kai, et al., and Calain, et al. (1993), J. Virol., 67(8): 4822-30.

Kai teaches sendai virus vectors for expression of, *inter alia*, growth factors including NGF (col. 3, paragraph 9 and col. 4, paragraph 8).

Calain teaches that transgenes are desireably located between the R1 and R2 loci, and following the rule of 6, as Applicant already acknowledges (Calain, e.g., ABSTRACT; Applicant's SPECIFICATION, p. 7, paragraph 3).

Hence, at the time of invention by Applicant, it would have been obvious to make a sendai viral vector comprising the NGF transgene between the R1 and R2 loci. The Artisan would have been motivated to do so because Kai teaches that these vectors may be used to make proteins inexpensively in large amounts by expression of the protein in a hen's egg using the vector. Moreover, the Artisan would have had a reasonable expectation of success as Kai had taught the use of the vectors, and Calain taught the location of the transgene.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,514,728 to Kai, et al., and Calain, et al. (1993), J. Virol., 67(8): 4822-30 as applied to claims 16-17 above, and further in view of any of Clements, et al. (1993) Oncogene, 8(5): 1311-16 (FGF-5), Teng, et al. (1998) Eur. J. Neurosci., 10: 798-802 (FGF-1 and FGF-2), or Hearn, et al. (1998) Dev. Biol., 197: 93-105 (GDNF).

As shown above, Claims 16-17 are obvious over that of Kai and Calain, however, Kai does not teach the specific proteins of FGF-1, FGF-2, FGF-5 or GDNF. On the other hand, each of the new references to this rejection supply evidence of one or more of the recombinant proteins being used to perform tests (ABSTRACTs of each reference).

Hence, at the time of the invention by Applicant, it would have been obvious to modify the invention of Kai/Calain to contain either the FGF-5, FGF-1, FGF-2, or GDNF of the appropriate reference. The Artisan would have been motivated to do so in order to inexpensively produce these proteins in large amounts in a hen's egg, to perform the experiments. The Artisan would have had a reasonable expectation of success, as Kai had already demonstrated the ability to produce proteins by such manner, and the various proteins had already been demonstrated to be capable of recombinant production, in the various references used.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patent No. 6,514,728 to Kai, et al., and Calain, et al. (1993), J. Virol., 67(8): 4822-30, and any of Kobayashi, et al. (1997) Exp. Brain Res., 116: 315-25 (BDNF) or Hudgins, et al. (1998) Exp. Neurol., 150: 171-82 (CNTF).

As shown above, Claims 16-17 are obvious over that of Kai and Calain, however, Kai does not teach the specific proteins of BDNF or CTNF. On the other hand, each of the new references to this rejection supply evidence of one or more of the recombinant proteins being used to perform tests (ABSTRACTs of each reference).

Hence, at the time of the invention by Applicant, it would have been obvious to modify the invention of Kai/Calain to contain either the BDNF or CNTF of the appropriate reference. The Artisan would have been motivated to do so in order to inexpensively produce these proteins in large amounts in a hen's egg, to perform the experiments. The Artisan would have had a reasonable expectation of success, as Kai had already demonstrated the ability to produce proteins by such manner, and the various proteins had already been demonstrated to be capable of recombinant production, in the various references used.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patent No. 6,514,728 to Kai, et al., and Calain, et al. (1993), J. Virol., 67(8): 4822-30, and any of Schendel, et al. (1997) Proc. Natl. Acad. Sci., USA., 94: 5113-18 (Bcl-2), Srinivasula, et al. (1996) Proc. Natl. Acad. Sci., USA., 93: 14486-91 (CrmA), Datta, et al. (1997) J. Biol. Chem., 272(3): 1965-69 (p35), or Duckett, et al. (1996) EMBO. J., 15(11): 2685-94.

Kai teaches that transgenes may be placed into a Sendai viral vector (col. 4, paragraph 2), and, as shown above, the Artisan would have found it obvious to place such transgene between the R1 and R2 loci, according to Calain. Kai teaches that such is to produce recombinant protein in large amounts and inexpensively (ABSTRACT).

Each of the other references, Schendel, Srinivasula, Datta, and Duckett teach the various other specifically claimed apoptotic inhibitors, HSPs, and peroxidases, as being made by recombinant methods (ABSTRACT of the various references).

At the time of invention by Applicant it would have been obvious to modify Kai/Calain to comprise the transgenes of the other references. The Artisan would have been motivated to do so in order to make the protein recombinantly in large amounts and inexpensively. Moreover, the Artisan would have had a reasonable expectation of success, as Kai had already demonstrated that proteins could be so-made in hen eggs, and the other references had demonstrated the proteins could be made recombinantly.

Claims Free of the Art

Due to Applicant's removal of the intended use in gene therapy, the Claims are now anticipated by the Art and subject to double-patenting, as was indicated in the prior official action of 8/10/05, p. 19, paragraph 2.

Conclusion

No Claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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